

## REMARKS

### **I. Introduction**

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claim 47 is requested to be cancelled without prejudice or disclaimer. Applicant reserves the right to pursue the subject matter of the cancelled claim at a later time, e.g., in a continuing application.

No claims are currently being amended.

No claims are being added.

This amendment adds, changes and deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, is presented, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 37-45 and 48-63 are now pending in this application.

### **II. The Rejection Under 35 U.S.C. 112 Has Been Mooted**

Claim 47 is rejected under 35 U.S.C. 112 as introducing new matter. Applicant does not concede that this rejection has proper basis. However, in the interest of expedience, claim 47 has been cancelled, thereby obviating this rejection.

### **III. The Rejections Under 35 U.S.C. 103 Should Be Withdrawn**

The Office Action has rejected claims 37-41, 44-48, 51-54, and 56-63 under 35 U.S.C. 103(a) as being unpatentable over Hei et al. (U.S. 6,544,727) in view of Brown (U.S. 4,530,691) in view of Kobashi (U.S. 5,428,993), in view of DeVries (U.S. PAT 4,379,452) and in view of Siegal (U.S. PAT 4,450,375). Applicant respectfully traverses.

Applicant initially notes that the obviousness rejection is based on numerous references from a variety of technical areas ranging from blood processing techniques to coffee brewing devices. Although the number and technical variety of references cited is not dispositive as to the propriety of a rejection under section 103, Applicant notes that the Supreme Court has warned against the danger hindsight in crafting an obviousness rejection:

A factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. See *Graham*, 383 U.S., at 36 (warning against a “temptation to read into the prior art the teachings of the invention in issue” and instructing courts to “ ‘guard against slipping into the use of hindsight’ ” (quoting *Monroe Auto Equipment Co. v. Heckethorn Mfg. & Supply Co.*, 332 F.2d 406, 412 [141 USPQ 549] (CA6 1964))). *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1397 (U.S. 2007).

Applicant’s respectfully submit that, in the current instance, the Office Action has fallen subject to the temptation of hindsight bias, and has used the teachings of Applicant’s claimed invention as a guide to select elements from disparate references to arrive at an a obviousness rejection. Accordingly, Applicant respectfully submits that there is no proper basis for the rejection.

Further, even assuming, *arguendo*, that the rejection does not suffer from the impermissible use of hindsight, Applicant respectfully submits that the proposed modification of Hei would not have been obvious to one skilled in the art at the time of the invention. The Office Action (page 6), relying on the disclosure of Hei et al. (henceforth “Hei”) in Figures 20 and 37; col. 97, lines 40-65, appears to identify Hei’s s fluid bags 201 and/or 301 as variable volume processing chambers. The Office Action admits that Hei does not show that these fluid bags are under the control of a controller, as required by Applicant’s claims. However, the Office Action (page 9) alleges:

It would have been obvious, to one of ordinary skill in the art, at the time the invention was made, to modify the system of Hei to include a processing chamber with a controllable variable-volume of Brown et al. because Brown et al shows a variable volume processing chamber advantageously provides an area of a blood sedimentation surface that is greater than an interface surface that maximizes

blood cell separation and minimizes platelet separation during red blood cell separation and collection. (*Emphasis added.*)

Applicant respectfully disagrees.

The variable volume processing chamber of Brown is located within a rotating centrifuge system. Brown (abstract) does state that:

The apparatus and chamber define an annular blood volume having a blood sedimentation surface and a cylindrical plasma volume having a cylindrical blood/plasma interface. The area of the blood sedimentation surface is greater than the interface area so as to maximize blood cell separation while minimizing platelet separation during the red blood cell separation collection.

However, Brown (column 5, line 33 through column 6, line 33) clearly teaches that the blood sedimentation process only occurs during the operation (i.e. rotation) of the centrifuge which drives the blood cell sediment to the chamber wall. Thus, it is only during the operation of the rotating centrifuge that the controllable volume chamber of Brown realizes the advantage of maximized blood cell separation and minimized platelet separation.

In contrast, the fluid bags 201 and/or 301 of Hei are not part of a rotating centrifuge. Instead, Hei describes these elements as fluid bags used for transfer of blood products by expressing the bag utilizing, e.g., a Fenwalim device for plasma expression, and not a control module for changing the processing chamber volume based on a volume of fluid in the processing chamber. (See, e.g. Hei, Example 18.) Thus a person skilled in the art would recognize that the controlled volume processing chamber of Brown, if employed in the device of Hei as proposed, would not result in the advantages (maximized blood cell separation and minimized platelet separation) set forth in the Office Action.

In view of this, Applicant respectfully submits that the proposed modification of Hei in view of Brown is based on an inaccurate characterization of the references. None of the remaining references (Kobayashi, DeVries, or Siegal) cure this deficiency. Accordingly, there is no proper basis for the rejection under 35 USC 103.

#### IV. Conclusion

Applicant believes that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by the credit card payment instructions in EFS-Web being incorrect or absent, resulting in a rejected or incorrect credit card transaction, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By 

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